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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/090,672	06/04/98	ISHIWATA T	766.21

005514 HM12/0215
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EXAMINER	
MAYO,K	
ART UNIT	PAPER NUMBER
1633	8

DATE MAILED: 02/15/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/090,672	Applicant(s) ISHIWATA et al.
	Examiner Kris Pelham May	Group Art Unit 1633

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-21* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-21* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☒ Notice to comply w/ sequence rules

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Applicant is given ONE MONTH, or THIRTY DAYS, whichever is longer, from the mailing date of this letter within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). In no case may an applicant extend the period for reply beyond the SIX MONTH statutory period. Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, 7, 10-13, 18, and 19, drawn to nucleic acids, method of using nucleic acids for detecting mRNA of an IgA nephropathy-related gene, an IgA nephropathy diagnostic agent, an IgA nephropathy therapeutic agent, vector, host cell, transformant, and method of using the transformant to produce protein, classified in class 536 , subclass 23.1, class 536, subclass 23.5, class 435, subclass 320.1, class 435, subclass 325, class 435, subclass 252.3, and class 435, subclass 69.1, for example.

II. Claim 6, drawn to a method of inhibiting transcription of an IgA nephropathy-related gene or translation of mRNA of an IgA nephropathy-related gene, classified in class 514 , subclass 44, for example.

III. Claim 8, drawn to a method of isolating a DNA related to IgA nephropathy from leukocytes, classified in class 435, subclass 6, for example.

IV. Claim 9, drawn to a protein having activity related to IgA nephropathy, classified in class 530, subclass 350, for example.

V. Claims 14-17, 20, and 21, drawn to an antibody, and a method of immunoassay, classified in class 530, subclass 386, and class 435, subclass 7.1, for example.

The inventions are distinct, each from the other because of the following reasons: Inventions I, IV, and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different

inventions are drawn to different compositions that have different functions and effects. The inventions are different because a polynucleotide, vector and host cell, a protein, and an antibody, all possess materially different physical and chemical properties, structures, and utilities. For instance, a nucleic acid can be used for detecting the presence of mRNA or DNA in a sample, whereas an antibody can be used for detection of a protein. Furthermore, there is nothing on record to indicate that these compositions are obvious variants. As such, the inventions are patentably distinct, and would encompass different search strategies and different considerations. The differences are further underscored by their divergent classification. Inventions I, II, III, and V are unrelated from invention IV because the various methods are materially different and plurally independent of the compositions. Furthermore, the methods of inventions I, II, III and V are unrelated to each other and patentably distinct each from the other, because they would require different process steps, reagents, and technical considerations. The search for any one of the methods would not be expected to reveal all the references relevant to the other methods. The search and examination, therefore, would be unduly burdensome.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

A telephone message was received from Mr. Lawrence Perry on 1/18/2000 making a provisional election. However, since a sequence letter is being sent to Applicant, an

accompanying written restriction requirement is also being sent. Applicant is requested to make a written response to the restriction requirement.

Applicant is advised that the response to this requirement must include an election of the invention to be examined, even though the requirement be traversed. (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kris Pelham Mayo, whose telephone number is (703)306-5877. The examiner can normally be reached on Monday-Thursday, and alternating Fridays from 8:00 a.m. to 5:00 p.m. (Eastern Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached at (703)308-0447. The FAX telephone number for group 1600 is (703)308-4242. An inquiry of a general nature or relating to the status of the application should be directed to the group receptionist whose telephone number is (703)308-0196.

Karen M. Hauda
Karen M. Hauda
Patent Examiner

Kris Pelham Mayo, D.V.M.
Patent Examiner
Art Unit 1633
February 1, 2000